

Gri-fill® System completes over 3000 media fills with NO positive growth

Media fills were used to simulate a worst case environment for a medium risk compounded sterile preparation. The following characteristics applied:

- Sterile source solutions were used with the Gri-fill® System
- All media was tested for growth promotion using the USP method for TSB
- No environmental controls were used (no hoods, no clean rooms)
- No special garb was used (no gloves, no gowns, no masks)
- No cleaning procedures were performed in the preparation areas other than general wiping of the counters before and after preparation
- Operators did wash their hands before compounding, however, no alcohol or disinfecting agent was used to clean the vial tops prior to spiking
- Every admixture had a minimum of 8 opportunities for contamination
- Opportunities for contamination (breaks in the system) ranged from 8 to 15 per completed media fill unit
- Glass vials were used to simulate worst case scenario of drawing room air into the source container for venting
- Operators were trained to use the equipment in one hour or less
- Completed media fill units were stored at room temperature for 7 days followed by incubation at 32 C for 7 days

The total media fill with the Gri-fill® System is an accumulation of three separate locations each performing three media fills. One location filled 600 units, a second location filled 1500 units and a third location filled 1050 units. There were No POSITIVES in any of the three locations.

At very low frequencies of failure rate, one needs to test a large number of samples to demonstrate acceptable results with statistical significance.¹

Here are a few examples to illustrate:

If....	We can say with 95% confidence that the contamination rate is no greater than ...
20 units are filled with 0 positives,	13.9%
600 units are filled with 0 positives,	0.5%
2996 units are filled with 0 positives,	0.1%
3150 units are filled with 0 positives,	0.095%

1. PDA Technical Monograph No. 2 1980

“To determine the number of units that need to be tested in order to have a 95% probability of detecting at least one failure [when the failure rates are so low] the following formula applies: $(x>0)=1-e^{-NP} >0.95$. The formula is valid where the failure rate is no larger than 0.1%. At the failure rate, N=2996 or about 3000 units need to be tested to be assured of a 95% probability of detecting at least one contaminated unit. At the 1% failure level, the test is deemed successful if no more than 3 contaminated units are observed out of 3000 tested.”